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Re: Patent Term Extension
Application for
U.S. Patent No. 4,303,651

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,303,651, issued December 1, 1981, which claims the human drug product FRAGMIN, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 26, 1995. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (2,832) + 723 \\ &= 2,139 \text{ days}\end{aligned}$$

Since the regulatory review period began March 31, 1985, after the patent issue date (December 1, 1981), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(B) applies in the present situation because the patent was issued before the date of enactment (September 24, 1984) of 35 U.S.C. § 156, but the date of an exemption under subsection 505(i) of the Federal Food, Drug and Cosmetic Act did not become effective until March 31, 1985. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(B), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of five years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,303,651
Granted:	December 1, 1981
Applicant:	Ulf P. F. Lindahl et al.
Owner of Record:	PHARMACIA AKTIEBOLAG
Title:	HEPARIN FRAGMENTS HAVING SELECTIVE ANTICOAGULATION ACTIVITY
Classification:	514/56
Product Trade Name:	FRAGMIN
Term Extended:	FIVE YEARS



Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: FRAGMIN
FDA Docket No.: 95E-0055

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